DETAILED ACTION

Claims 1-30 are pending in the instant application.

Information Disclosure Statement

Applicants' Information Disclosure Statements, filed 08/17/2006, 06/18/2008, 06/27/2008, 06/30/2008, 08/13/2008, and 03/03/2009 have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

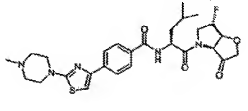
Priority

This application is 371 of PCT/GB05/50003 filed on 01/06/2005, which claims foreign priority of Sweden Patent Application Nos. 0400022-0 and 0401332-2 filed on 01/08/2004 and 05/26/2004 respectively.

Declaration under Rule 37 C.F.R. §1.132

Applicants' submission of the Declaration under Rule 37 C.F.R. §1.132, filed on 11/14/2008 has been entered.

Response to Restriction/Election

Applicant's election with traverse of Group I (i.e. claims 1-28) and elected species of the compound  as Example 8.19 shown at

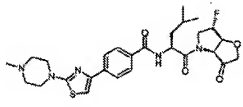
page 57 of the specification in the interview on 05/25/2010 is acknowledged. Applicants' traverse is on the ground that search and examination of Group (I) and (II) will not cause a serious burden to the Office. Applicants' argument has been fully considered, but is not persuasive. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed could be used in a materially different process of using that product for treating osteoporosis, gingival diseases, metabolic bone disease, etc., as demonstrated throughout the specification, which are directed to several different methods of using the product. The process as claimed could be used in materially different products of using those products as demonstrated throughout the specification, which are directed to several different compounds of using the process, which requires searching at different criteria at different commercial databases. It would be burden for the Examiner if the application were not restricted. However, the withdrawn method (process) claims are subject to rejoin product claims if the process claims are commensurate in scope with an allowable product claim, and complied with the requirement under 35 U.S.C. 1st and 2nd paragraphs. Therefore, the restriction requirement is maintained.

Status of the Claims

Claims 29 and 30 are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement.

Specification

The specification contains errors. Specifically, the name of Example 8.18 at lines 19-20, page 68 of the specification does not correspond to the chemical structure of

Example 8.18  . Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 1-28 are rejected due to claiming a "prodrug" of a compound of Formula (I). According to Wikipedia, prodrugs

can be classified into two types based on their sites of conversion into the final active drug form: Type I, those that are converted intracellularly (e.g., anti-viral nucleoside analogs, lipid-lowering statins, antibody-directed/gene-directed enzyme prodrugs [ADEP/GDEP] for chemotherapy), and Type II, those that are converted extracellularly, especially in digestive fluids or the systemic circulation (e.g., etoposide phosphate, valganciclovir, fosamprenavir). Both types can be further categorized into subtype A or B, based on additional criteria. Those for the Type IA and IB are whether or not the cellular converting location is the site of therapeutic action. For the Type IIA and IIB, they are categorized depending on whether the conversion occurs in the gastrointestinal (GI) fluids or systemic circulation, *Wu and Farrelly, Toxicology 236:1-6, 2007*. However, such "prodrug" of the Formula **(I)** is not described in the specification to reasonably convey one skilled in the art. Therefore, the specification fails to comply with the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in claim 1, the definition of $\mathbf{R^9}$ is defined by $\mathbf{R^{10}}$, and $\mathbf{R^{10}}$ is in turn defined by $\mathbf{R^9}$ in a circular way, which renders the claims indefinite.

Conclusion

- Specification is objected to.
- Claims 1-28 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu, *Ph.D.*, whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu/

Primary Patent Examiner
Art Unit 1626